

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 135.72, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 202, “Certificate of Need Program,” and to rescind Chapter 204, “Uniform Reporting Requirements,” Iowa Administrative Code.

These proposed amendments were approved by the State Health Facilities Council on July 21, 2014.

The proposed amendments update and clarify the rules for the Certificate of Need (CON) Program. Item 1 rescinds and replaces rule 641—202.1(135), the definition portion of Chapter 202, so that definitions will be listed alphabetically. The following new definitions are added to the new rule: “acute care category of bed usage,” “cardiac catheterization service,” “open heart surgical service,” “physical facility,” and “radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment.” The definitions of “appropriate geographic service area,” “bed capacity” and “organ transplantation service,” which are in the current rule, are included and updated in the new rule. In addition, the definition of “consumer” in the existing rule is omitted from the new rule. Item 4 describes the process for requesting a determination of whether a proposal requires a CON Program review. Item 18 relates to reporting requirements, some of which are currently addressed in outdated Chapter 204, which is rescinded in Item 20. The remaining items amend terminology, encourage electronic submission of material and indicate that forms and notifications are posted on the CON Program Web page.

Any interested person may make written comments or suggestions on the proposed amendments on or before October 21, 2014. Such written comments should be directed to Barb Nervig, Certificate of Need Program, Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. E-mail may be sent to barbara.nervig@idph.iowa.gov.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 135.61 to 135.79.

The following amendments are proposed.

ITEM 1. Rescind rule 641—202.1(135) and adopt the following **new** rule in lieu thereof:

641—202.1(135) Definitions. For purposes of this chapter, the following definitions apply:

“*Acute care category of bed usage,*” as the term applies in Iowa Code section 135.63(2)“k,” shall be the same as the acute care categories listed in the state survey section of the American Hospital Association Annual Survey of Hospitals.

“*Any expenditure in excess of five hundred thousand dollars,*” as defined in Iowa Code section 135.61(18)“e,” means new capital expenditures and new personnel necessary to operate the service for a year.

“*Any mobile health service with a value in excess of one million five hundred thousand dollars,*” as defined in Iowa Code section 135.61(18)“l,” means the value of all equipment used to provide the service, including the trailer. The party providing the equipment shall be the applicant regardless of the location of that party.

“*Appropriate geographic service area,*” as the term applies to defining affected persons in Iowa Code section 135.61(1)“c,” shall be defined as follows:

1. For applications regarding hospitals, hospitals located in the same county and in Iowa counties contiguous to the county wherein the applicant hospital’s proposed project will be located.

2. For applications regarding health care facilities, other health care facilities located in the same county and in Iowa counties contiguous to the county wherein the applicant's proposed health care facility will be located.

3. For applications sponsored by other than the hospitals or health care facilities specified in paragraphs "1" and "2," those providers within the same county who offer similar service or might logically be viewed as potential providers of such service.

"Bed capacity" shall be defined as follows:

1. For hospitals, bed capacity is defined as the total facility licensed beds as reported on the state survey section of the American Hospital Association Annual Survey of Hospitals.

2. For health care facilities, bed capacity is defined as a facility's licensed bed capacity according to the department of inspections and appeals.

"Cardiac catheterization service," as the term applies to a new or changed institutional health service in Iowa Code section 135.61(18) "m"(1), means the initiation or expansion of this service.

"Consumers served by a new institutional health service" means those consumers residing in the service area as determined by the department.

"Long-term (acute) care hospital," for purposes of these rules, means a hospital that has been approved to participate in the Title XVIII (Medicare) program as a long-term care hospital-prospective payment system hospital (LTCH-PPS) in accordance with 42 CFR Part 412.

"Open heart surgical service," as the term applies to new or changed institutional health service in Iowa Code section 135.61(18) "m"(2), means the initiation or expansion of this service.

"Organized outpatient health facility," as defined in Iowa Code section 135.61(20), shall include, but not be limited to, the following types of facilities:

1. Community mental health centers; and
2. Comprehensive outpatient rehabilitation facilities (CORFs) certified by Medicare.

"Organ transplantation service," as the term applies to a new or changed institutional health service in Iowa Code section 135.61(18) "m"(3), means the initiation or expansion of this service. Each type of organ transplant shall be considered separately.

"Permanent change in bed capacity of an institutional health facility" means a change which is intended to be effective for one year or more.

1. A conversion of a long-term acute care hospital or a rehabilitation hospital as defined by federal regulations to a general acute care hospital or to a different type of specialty hospital is a permanent change in bed capacity and requires a certificate of need.

2. A hospital which has deleted beds pursuant to Iowa Code section 135.63(2) "g" for the purpose of receiving designation as a critical access hospital may reestablish the deleted beds at a later time without obtaining a certificate of need, provided that the number of beds reestablished does not exceed the number of beds maintained prior to the deletion as reported on the bed reduction form.

"Physical facility," as the term applies in Iowa Code section 135.61(18) "f," means a separately licensed facility.

"Private offices and private clinics of an individual physician, dentist, or other practitioner or group of health care providers." The meaning of this term as used in Iowa Code section 135.63(2) "a" shall be determined by looking at factors which include, but are not limited to:

1. The type of health care service delivered;
2. The control and supervision of medical judgment in the care of and treatment of patients;
3. The control and supervision of professional assistants, including nurses, physician assistants, and technicians; and
4. The ownership and maintenance of medical records of patients.

"Radiation therapy service applying ionizing radiation for the treatment of malignant disease using megavoltage external beam equipment," as the term applies to new or changed institutional health service in Iowa Code section 135.61(18) "m"(4), means the initiation or expansion of this service.

"Rehabilitation hospital," for the purposes of these rules, means a hospital that has been approved to participate in the Title XVIII (Medicare) program as an inpatient rehabilitation facility-prospective payment system hospital (IRF-PPS) in accordance with 42 CFR Part 412.23(b), 412.25 or 412.29.

“Relocation of an institutional health facility,” as the term applies to new or changed institutional health service in Iowa Code section 135.61(18) “b,” means the replacement of a facility located in one county with a facility located in another county.

“Value in excess of one million five hundred thousand dollars,” as used in Iowa Code section 135.61(18) “g,” “h,” “i” and “j,” means the value of the equipment including any applicable sales tax, delivery charge and installation charge.

ITEM 2. Amend subrule 202.2(1) as follows:

202.2(1) Before applying for a certificate of need, the sponsor of a proposed new institutional health service or changed institutional health service shall submit a letter of intent to the department. The letter of intent shall contain the following:

- 1- a. A brief description of the ~~proposal~~ proposed project;
- 2- b. ~~Project’s~~ The project’s location;
- 3- c. ~~Its~~ The project’s estimated cost (site costs, land improvements, facility costs, movable equipment and financing costs); and
- 4- d. An explanation of how the project will be financed.

ITEM 3. Amend subrule 202.2(3) as follows:

202.2(3) The department shall make available ~~to each applicant any and on the certificate of need~~ Web page located on the department’s Web site, www.idph.state.ia.us, all criteria and standards which are pertinent to a particular an application. This shall be done within 15 calendar days of receipt of a letter of intent or upon request.

ITEM 4. Rescind rule 641—202.3(135) and adopt the following **new** rule in lieu thereof:

641—202.3(135) Determination of reviewability. A sponsor of a proposed project may submit a written request for a determination of reviewability as to whether the project requires a certificate of need.

202.3(1) The request should include sufficient details of the proposed project and cite the sections of the Iowa Code that the sponsor relies upon to assert the project is not reviewable.

202.3(2) Upon receipt of a written request from the sponsor of a project, the department shall determine if a proposed project requires a certificate of need under Iowa Code sections 135.61 to 135.83. The department may request additional information about the project to make the determination.

a. If it is determined that a certificate of need is required, the sponsor shall be notified by the department and the request for nonreviewability shall be considered the letter of intent for purposes of subrule 202.2(2).

b. If it is determined that a certificate of need is not required, the sponsor shall be notified by the department and the determination of nonreviewability shall be placed on the next agenda of the state health facilities council for consideration.

c. The notification to the sponsor of the results of the department’s review of the request shall include specific Iowa Code citations relied upon to support the determination.

ITEM 5. Amend subrule 202.4(1) as follows:

202.4(1) Application form.

a. ~~The statement of information required by the department for purposes of review shall be the information requested on the department’s application form. A sponsor of a proposed project for a new or changed institutional health service shall submit to the department an application for certificate of need by using the appropriate application form found on the certificate of need Web page located on the department’s Web site, www.idph.state.ia.us. All information requested in the application form will be required in the absence of a written waiver by the department.~~

b. An original application and six copies thereof shall be sent to the Certificate of Need Program, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. An electronic copy of the application and all attachments shall also be submitted.

c. No change.

ITEM 6. Amend subrule 202.4(2) as follows:

202.4(2) Application fee.

~~a.~~ The application shall be accompanied by a fee equivalent to three-tenths of 1 percent of the anticipated cost of the project. There shall be a minimum fee of \$600 and a maximum fee of \$21,000.

~~b. a.~~ The fee shall be based on the total cost of the project, which shall include site costs, land improvements, facility costs, movable equipment and financing costs.

~~b.~~ Fee The fee for leased or donated new institutional health services ~~would~~ shall be calculated in the same manner as if the new institutional health services were purchased.

(1) The leased equipment fee shall be based on total value of the lease, plus sales tax, delivery and installation.

(2) The lease of space includes the cost of a one-year-lease payment for the space in addition to other costs associated with the project.

(3) Financing costs shall not be applicable on leases or cash purchases.

c. The fee shall be remitted by check ~~or money order~~ made payable to the Treasurer, State of Iowa, and addressed to Iowa Department of Public Health—Certificate of Need, Lucas State Office Building, Des Moines, Iowa 50319-0075.

d. and e. No change.

f. An applicant for a new or changed institutional health service offered or developed by an intermediate care facility for ~~the mentally retarded or the mentally ill~~ persons with an intellectual disability or for persons with a mental illness is exempt from payment of the application fee.

g. No change.

ITEM 7. Amend subrule 202.4(4) as follows:

202.4(4) Promptly after an application is accepted, the department shall provide written notification to all affected persons defined in Iowa Code section 135.61(1) “c” and “d” which are identified ~~in the department’s data banks~~ on the department of inspections and appeals Web site or by the applicant, as provided in Iowa Code section 135.66(2). The department shall notify other affected persons by ~~distribution of pertinent information to the news media~~ posting such notification to the certificate of need Web page located on the department’s Web site, www.idph.state.ia.us. The notice and the Web page shall identify deadlines for the submission of written materials as provided in 202.6(2).

ITEM 8. Amend paragraph **202.4(5)“b”** as follows:

b. All reports shall be ~~mailed~~ provided to council members and to the applicant ~~at least ten calendar days~~ prior to the health facilities’ council meeting at which the application is to be heard.

ITEM 9. Amend subrule 202.5(4) as follows:

202.5(4) The council shall, at the ~~July first~~ first meeting after July 1 of each odd-numbered year, elect a vice-chairperson, who shall perform the duties of the chairperson in the absence of the chairperson, when the chairperson has a conflict of interest or when the chairperson so directs.

ITEM 10. Renumber subrule **202.5(5)** as **202.5(6)**.

ITEM 11. Adopt the following new subrule 202.5(5):

202.5(5) The department shall notify the public and affected parties of the council meeting agenda utilizing the certificate of need Web page located on the department’s Web site, www.idph.state.ia.us.

ITEM 12. Amend subrule 202.6(2) as follows:

202.6(2) The notice of an accepted application issued pursuant to Iowa Code section 135.66(2) shall inform the applicant and affected persons of the deadlines for the submission to the department of written statements or other materials. These deadlines will also be posted on the certificate of need Web page on the department’s Web site, www.idph.state.ia.us.

a. Written submissions received by the department after the deadlines established in this notice shall not be considered by the department or the council unless submitted at the public hearing solely to support oral testimony or upon a showing of good cause.

b. Applicants and affected persons shall submit ~~six copies of~~ all written materials electronically. If electronic submission is not possible, then an original and six copies must be submitted.

ITEM 13. Amend subrules 202.7(1) and 202.7(2) as follows:

202.7(1) If an applicant desires to request a summary review of its application for a certificate of need, it shall submit a written request for summary review, an original application and six copies thereof to the Certificate of Need Program, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075. An electronic copy of the application and all attachments shall also be submitted. The applicant is not required to submit a letter of intent pursuant to Iowa Code section 135.65 prior to submitting a written request for a summary review.

202.7(2) The eligibility of an application for summary review pursuant to Iowa Code section 135.67 shall not mandate or require such review. The department will make the decision as to whether an application will be reviewed in the summary review process is the department's.

ITEM 14. Rescind paragraph **202.11(1)“a”** and adopt the following new paragraph in lieu thereof:

a. A decision by the department pursuant to 641—202.3(135) that a proposed project does not require a certificate of need;

ITEM 15. Amend subrule 202.11(2) as follows:

202.11(2) The following stages of the process are final decisions subject to judicial review as final agency action under Iowa Code section 17A.19:

a. A decision by the department to disallow summary review;

b. A decision by the council that a proposed project does not require a certificate of need;

~~b. c.~~ A decision by the council to approve or deny an application; ~~and~~

~~c. d.~~ The council's final ruling on an application for rehearing; ~~and~~

e. A decision by the council to revoke a certificate of need pursuant to 641—202.13(135).

ITEM 16. Amend subrule 202.12(1) as follows:

202.12(1) ~~Progress reports of all approved projects shall be submitted~~ The sponsor of an approved application shall submit a progress report using the form available on the certificate of need Web page on the department's Web site, www.idph.state.ia.us, to the department six months after approval at hearing.

ITEM 17. Amend subrules 202.13(1) to 202.13(3) as follows:

202.13(1) ~~Requests for extension of a certificate of need must be filed in letter form to the department from the applicant no later than 45 days prior to the expiration of the certification. A request by the applicant for an extension of a certificate of need must be filed with the department using the form available on the certificate of need Web page on the department's Web site, www.idph.state.ia.us, no later than 30 days prior to the expiration of the certificate of need.~~

202.13(2) ~~Request~~ A request for extension shall fully identify the project and indicate the current status of the project in descriptive terms.

202.13(3) ~~The department shall use the news media to notify the public and affected parties of the council meeting agenda, including extension requests. The news media shall be notified at least ten days before the council meeting.~~

Any affected persons shall have the right to submit to the department in writing, or orally at the council meeting at which the extension request is considered, information which may be relevant to the question of granting an extension.

ITEM 18. Adopt the following new rule 641—202.16(135):

641—202.16(135) Reporting requirements. For the purposes of the annual reports and data compilation required in Iowa Code sections 135.75 and 135.78, the department will utilize the AHA Annual Survey of Hospitals with the state survey addendum for hospitals and the cost reports for health care facilities submitted to the Medicaid enterprise of the department of human services.

ITEM 19. Amend **641—Chapter 202**, implementation sentence, as follows:

These rules are intended to implement Iowa Code ~~chapter 135~~ sections 135.61 to 135.79 and 135.83.

ITEM 20. Rescind and reserve **641—Chapter 204**.